

REMARKS

Applicant respectfully requests favorable reconsideration of this application, as amended.

After entry of this amendment, claims 81-102 and 105-117 are pending, with claims 112-117 being added by this amendment.

Claims 81-83, 85-99, 101, 102, 105-107, and 109 presently stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Fletcher-Haynes et al. (US 2001/0034614) in view of Tsoglin et al. (US 5,469,859). Claims 84, 108, 110, and 111 presently stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Fletcher-Haynes in view of Tsoglin, and further in view of Kleinekofort (US 6,827,698).

Without acceding to the outstanding rejections, independent Claims 81, 90 and 97 have been amended more clearly to set forth certain distinctive features of Applicant's invention. Applicant respectfully proposes that the independent claims distinguish patentably from the applied references.

Each of the claims requires at least a variation of the following:

- A programmable treatment unit and a programmable monitor unit with respective controls and physically located to be accessible simultaneously by an operator.
- The monitor unit is configured to monitor only the single treatment unit.
- The monitor unit can have its program modified from a remote device.

Fletcher-Haynes is directed to an extracorporeal blood processing information management system. The information management system of Fletcher-Haynes is described as having a central server. Fletcher-Haynes does not teach a treatment and monitor unit positioned together for simultaneous physical access as well as exclusive

connection of the monitor unit to the single treatment unit. The server is a central server for providing central or remote access to information from apheresis machines and there is no teaching of the claimed combination.

Further, in contrast to the claims, the central server of Fletcher-Haynes is adapted to communicate with multiple apheresis machines and to control the operation of the apheresis machines without functional isolation. In particular, the central server of Fletcher-Haynes can communicate operational programming information via a two-way communications link to an apheresis machine. In fact, Fletcher-Haynes mentions that “donor-related data and/or initial procedure order is preferably generated by the central computer/database assembly 140 and then **transferred to one of the apheresis machines** 10 (via an RS/232 or other similar interface [...]).” Fletcher-Haynes, paragraph [0061] (emphasis added).

This is in contrast to Applicant’s invention in which there is a one-way communication mechanism operatively connecting the treatment unit to the monitor unit such that the monitor unit is prevented from sending signals to the treatment unit at all times during operation of the medical treatment device and such that the monitor unit receives data from the treatment unit, as recited in Claim 81 for example.

Furthermore, there is no teaching or suggestion in Fletcher-Haynes of the central computer preventing the monitoring unit from modifying the program of the treatment unit.

Tsoglin, a secondary reference relied upon to supply the deficiencies of Fletcher-Haynes, is directed to a non-invasive method and device for collecting measurements representing body activity and determining cardiorespiratory parameters of the human body based upon the measurements collected. Tsoglin describes a communications link

for electrically isolating a patient (e.g., an opto-coupler), however, Tsoglin does not describe restricting a communications link to one-way operation. Tsoglin contains no teaching or suggestion of a one-way communications link in the specific context defined by the claims.

Substituting the two-way communications link of Fletcher-Haynes (for example, an RS-232 link) with an opto-coupler would merely result in an electrically isolated two-way communications link. Such a two-way link is evidently not a one-way communication mechanism operatively connecting a treatment unit to a monitor unit such that the monitor unit is prevented from sending signals to the treatment unit at all times during operation of a medical treatment device and such that the monitor unit receives data from the treatment unit, as recited in Claim 81. Nor would the combination of Fletcher-Haynes and Tsoglin provide a monitor unit having computer software instructions stored in a memory device of the monitor unit, the monitor unit being configured to be programmable by modification of the computer software instructions, wherein the modification of the computer software instructions and subsequent operation of the monitor unit according to the modified software instructions is prevented from altering the operation of the treatment unit, as recited in Claim 81.

Also, the combination of Fletcher-Haynes and Tsoglin would not result in a medical treatment device in which the monitor unit is configured to receive data exclusively from the treatment unit, as recited in the claims.

Thus, whether viewed individually or in combination, Fletcher-Haynes and Tsoglin fail to teach or suggest the above-mentioned features of the claims.

Kleinekofort, another secondary reference applied in the rejection of certain dependent claims, fails to remedy the deficiencies of Fletch-Haynes and Tsoglin discussed above.

The claims also specify that the monitor unit is in communication with a remote unit which can upgrade its program.

Applicant respectfully requests an early Notice of Allowance.

Should the Examiner believe that any further action is necessary to place this application in better form for allowance, the Examiner is invited to contact Applicants' representative at the telephone number listed below.

The Commissioner is hereby authorized to charge to Deposit Account No. 50-1165 (T4342-14521US01) any fees under 37 C.F.R. §§ 1.16 and 1.17 that may be required by this paper and to credit any overpayment to that Account. If any extension of time is required in connection with the filing of this paper and has not been separately requested, such extension is hereby requested.

Respectfully submitted,

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